

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: TBD		
2. Request for Proposal (RFP) Number:  N02AT67007-C16	3. Issue Date:  March 11, 2016	4. Set Aside: [X] No [ ] Yes See Part IV Section L
5. Title : Clinical Studies Monitoring Service (CSMS) National Center for Complementary and Integrative Health (NCCIH)		
6. ISSUED BY: Office of Acquisitions National Cancer Institute National Institutes of Health Department of Health and Human Services 8490 Progress Drive, Suite 400 Riverside 5 Room 4046 Frederick, MD 21701		7. SUBMIT OFFERS TO:  See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 2:00PM local time on April 11, 2016. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.  IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at <a href="http://www.sam.gov">http://www.sam.gov</a>		
11. FOR INFORMATION CALL: Mary Muir Loesch PHONE: 301-624-8764 e-MAIL: <a href="mailto:mary.loesch@nih.gov">mary.loesch@nih.gov</a> COLLECT CALLS WILL NOT BE ACCEPTED.		
The deadline for receipt of all questions concerning this RFP is 3:00PM EDT, March 25, 2016		C. Timothy Crilley Contracting Officer Office of Acquisitions <a href="mailto:tcrilley@mail.nih.gov">tcrilley@mail.nih.gov</a>

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## PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

## SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

### ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

To provide comprehensive clinical site and study monitoring service for the NCCIH extramural clinical studies research portfolio and other support efforts. To perform specialized clinical site visits, to be conducted independently or in conjunction with other clinical monitoring site visits.

### ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

### ARTICLE B.3. ESTIMATED COST - OPTION

- a. The estimated cost of the Base Period of this contract is \$TBD.
- b. The fixed fee for the Base Period of this contract is \$TBD. For level of effort contracts: The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.
- c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is \$TBD.
- d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost (\$)
Base Period	TBD
Option Period 1	TBD
Option Period 2	TBD
Option Period 3	TBD
Option Period 4	TBD

	<b>Estimated Cost (\$)</b>
Total [Base Period and Option(s)]	TBD

Payment of fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

The fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended.

#### **ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS**

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Consultant Costs; 9) Subcontract Costs; 10) Patient Care Costs; 11) Accountable Government Property; 12) Printing costs; and 13) Research Funding.

#### **ARTICLE B.5. ADVANCE UNDERSTANDINGS**

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

### **SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

#### **ARTICLE C.1. STATEMENT OF WORK**

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated February 12, 2016, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).
- b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Contracting Officer's Representative (COR).

#### **ARTICLE C.2. REPORTING REQUIREMENTS**

All reports required herein shall be submitted in electronic format.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Making Files Accessible."

All reports required herein shall be submitted in an electronic format via email as attachments to the following NCI

Branch Distribution Mailbox:

[ncibranchcinvoices@mail.nih.gov](mailto:ncibranchcinvoices@mail.nih.gov)

NOTE: Hard copies of reports are no longer required and shall no longer be mailed to the NCI OA. Each email submission shall contain only one deliverable. If the attached file for the deliverable exceeds 50MB, the contractor shall divide the deliverable into files of 50MB each. All deliverables should be limited to five file attachments or less. In cases where it is necessary, more than five attachments will be accepted.

The subject line of the email shall read as follows:

Deliverable\_Contract Number\_Vendor's Name\_Deliverable Description\_Due Date

All data transfer of PII or sensitive information to the NCI must be encrypted.

**a. Technical Progress Reports**

1. In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports during the period of performance of this contract:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

**1. Quarterly Progress Report**

a. The report shall include on the results of internal QNQC to the CO and COR, including all deficiencies and problems identified recommended approaches/actions to be taken to correct deficiencies and resolve problems, and any recommended modifications to the QNQC Plan. All QNQC Plan modifications must be approved by the COR prior to implementation. The reports shall also provide a general overview of the project to date and any outstanding issues that need addressed. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

b. The first report shall be due December 15, 2016. Thereafter, reports shall be due on or before the 15th Calendar day following each reporting period.

**2. Final Report**

This report shall consist of the work performed and results obtained for the entire contract period of performance as stated in SECTION F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period. Quarterly report shall not be required for the period when the Final Report is due.

**b. Other Reports/Deliverables**

**1. Report of USDA-Designated Biobased Products**

In accordance with FAR clause 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts, the contractor shall report to <http://www.sam.gov>, with a copy to the Contracting Officer any USDA-designated biobased products purchased during the period of October 1-September 30 of each contract year. This report shall be submitted no later than October 31 of each year during contract performance and **on the expiration date of the contract.**

**a. Roster of Employees Requiring Suitability Investigations**

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. (Reference subparagraph A.e. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

**b. Reporting of New and Departing Employees**

The Contractor shall notify the Contracting Officer's Representative (COR) and Contracting Officer within five working days of staffing changes for positions that require suitability determinations as follows:

- a. New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
- b. Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COR and/or Contracting Officer upon request.

(Reference subparagraph E.2.a-c. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

- c. Contractor - Employee Non-Disclosure Agreement(s)** The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: <https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf>.

(Reference subparagraph E.3.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

**2. Section 508 Annual Report**

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: <http://www.hhs.gov/web/508/contracting/technology/vendors.html> under "Vendor Information and Documents."

**3. Standard Operating Procedures (SOPs)**

Draft Standard Operating Procedures (SOPs) governing all aspects of the conduct of both routine and specialized clinical site monitoring visits. Draft SOPs are due within twenty-one (21) calendar days of the contract effective date, submit, for COR review and approval.

Final Standard Operating Procedures (SOPs) governing all aspects of the conduct of both routine and specialized clinical site monitoring visits. The final SOPs are due within fifteen (15) calendar days of receipt of COR comments on the draft plan.

#### **4. All Site Visit Reports (Draft)**

Draft Site Visit Reports as outlined in the SOW. Reports are due within ten (10) calendar days of completing site visit.

#### **5. All Site Visit Reports (Final)**

Final Site Visit Reports as outlined in the SOW. Reports are due within two (2) business days of completing site visit.

#### **6. Approval/Disapproval of Site Submitted Action Item Form (AIF)**

AIF Reports as outlined in the SOW. Reports are due no later than three (3) business days after receipt from site.

#### **7. Training Plan**

Draft Training Plan as outlined in the SOW. Draft training plan is due within twenty-one (21) calendar days of the contract effective date.

Final Training Plan shall be submitted and implemented within forty (40) calendar days of receipt of COR comments on the draft plan.

#### **8. Quality Assurance/Quality Control (QA/QC) Plan**

Draft Quality Assurance/Quality Control (QA/QC) Plan as outlined in the SOW. Draft QA/QC is due within six (6) weeks of the contract effective.

Final Quality Assurance/Quality Control (QA/QC) Plan as outlined the SOW. Final QA/QC Plan shall be submitted within four (4) weeks of receipt of COR comments on the draft QA/QC.

#### **9. Ad-Hoc Reports**

a. Quarterly List of Site Monitoring Special Assignments -providing an inventory of all forthcoming special assignments requested.

b. Bi-monthly Institutional Review Board (IRB) Lapse of Review Report- providing an inventory of all lapses of IRB review with regard to lack of compliance to GCP guidelines.

c. Quarterly Co-monitoring Requests Report- providing an inventory of all quarterly site monitoring assignments with 2 monitors designated for the assignment.

#### **10. Transition Plans Reporting**

Within fourteen (14) calendar days of the contract effective date, develop and submit, for COR review and approval, a Draft Initial Transition Plan to ensure full assumption of all contract responsibilities and functions no later than three (3) months following the contract effective date. The Draft Initial Transition Plan shall delineate the transition activities to be undertaken, timelines for the completion of each transition activity, and the staff to be assigned. Revise the Draft Initial Transition Plan to accommodate COR comments, and submit the Final initial Transition Plan no later than six (6) weeks after receipt of COR comments.

## **11. Option Implementation Plan**

Draft Option Implementation Plan: Due six (6) weeks before exercising of an Option, develop and submit, for COR and Contracting Officer review, a Draft Option Implementation Plan consisting of the following:

The COR and the Contracting Officer will review and provide comments on the Draft Option Implementation Plan within four (4) weeks of receipt. The Contractor shall revise the Draft Option Implementation Plan to address comments and modifications received, and submit the Final Option Implementation Plan within three (3) weeks of receipt of comments.

## **12. Integrated Master Project Plan (IMPP)**

IMPP Reports as outlined in the SOW. Reports are due within four (4) weeks of contract effective date.

## **13. Site Monitoring Services Distribution (Draft)**

Draft Site Monitoring Services Distribution Reports as outlined in the SOW. Reports are due within four (4) weeks of contract effective date.

## **14. Site Monitoring Services Distribution- (Final)**

Final Site Monitoring Services Distribution Reports as outlined in the SOW. Reports are due within eight (8) weeks of contract effective date.

## **15. Management Structure (Draft)**

Draft Management Structure Reports as outlined in the SOW. Reports are due within four (4) weeks of contract effective date.

## **16. Management Structure (Final)**

Final Management Structure Reports as outlined in the SOW. Reports are due within eight (8) weeks of contract effective date.

## **17. Project Implementation and Management (Draft)**

Draft Project Implementation and Management Reports as outlined in the SOW. Reports are due within eight (8) weeks of contract effective date.

## **18. Project Implementation and Management (Final)**

Final Project Implementation and Management Reports as outlined in the SOW. Reports are due within three (3) months of contract effective date.

## SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

## SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, TBD is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:

National Center for Complementary  
and Integrative Health (NCCIH)  
National Institutes of Health  
Department of Health and Human Services  
6707 Democracy Blvd, Suite 400  
Bethesda, MD 20892

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

## SECTION F - DELIVERIES OR PERFORMANCE

### ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from August 31, 2016 through August 30, 2017.
- b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period of Performance
Option Period 1	August 31, 2017 - August 30, 2018
Option Period 2	August 31, 2018 - August 30, 2019
Option Period 3	August 31, 2020 - August 30, 2021
Option Period 4	August 31, 2021 - August 30, 2022

### ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the DESCRIPTION-SPECIFICATION-WORKSTATEMENT -STATEMENT OF WORK Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract:

<b>Item</b>	<b>Description</b>	<b>Quantity</b>	<b>Delivery Schedule</b>
(1)	Quarterly Report	<b>One Electronic Copy</b>	Due on the 15th calendar day following the end of the quarterly period
(2)	Final Report	<b>One Electronic Copy</b>	Due on the anniversary date of the contract or the option anniversaries if exercised
(3)	Standard Operating Procedures (SOPs)	<b>One Electronic Copy</b>	Draft SOPs due within twenty-one (21) calendar days of the contract effective date. Final SOPs due within fifteen (15) calendar days of receipt of COR's comments
(4)	All Site Visit Reports (Draft)	<b>One Electronic Copy</b>	Draft report due no later than ten (10) business days
(5)	All Site Visit Reports (Final copy)	<b>One Electronic Copy</b>	Final copy due to the site no later than two (2) business days following receipt of draft document
(6)	Approval/Disapproval of Site submitted Action Item Form (AIF)	<b>One Electronic Copy</b>	Due no later than three (3) business days after receipt from site
(7)	Training Plan	<b>One Electronic Copy</b>	Draft plan due within twenty-one (21) calendar days of the contract effective date. Final plan due within forty (40) calendar days of receipt of the COR's comments
(8)	Quality Assurance/Quality Control (QA/QC) Plan	<b>One Electronic Copy</b>	Draft plan due within six (6) weeks of the contract effective date. Final plan due within four (4) weeks of receipt of the COR's comments
(9)	Ad-Hoc Reports	<b>One Electronic Copy</b>	As determined by the COR
(10)	Transition Plans	<b>One Electronic Copy</b>	Draft plan due within fourteen (14) calendar days of the contract effective date. Final plan due no later than six (6) weeks after receipt of the COR's comments
(11)	Option Implementation Plan	<b>One Electronic Copy</b>	Draft plan due within six (6) weeks of the exercise of option. Final plan due within three (3) weeks of receipt of the COR's comments

Item	Description	Quantity	Delivery Schedule
(12)	Section 508	<b>One Electronic Copy</b>	Due annually on/or before the anniversary date of the contract
(13)	Integrated Master Project Plan (IMPP)	<b>One Electronic Copy</b>	Due within four (4) weeks of contract effective date.
(14)	Draft Site Monitoring Services Distribution	<b>One Electronic Copy</b>	Due within four (4) weeks of contract effective date.
(15)	Final Site Monitoring Services Distribution	<b>One Electronic Copy</b>	Due within eight (8) weeks of contract effective date.
(16)	Draft Management Structure	<b>One Electronic Copy</b>	Due within four (4) weeks of contract effective date.
(17)	Final Management Structure	<b>One Electronic Copy</b>	Due within eight (8) weeks of contract effective date.
(18)	Draft Project Implementation and Management	<b>One Electronic Copy</b>	Due within eight (8) weeks of contract effective date.
(19)	Project Implementation and Management	<b>One Electronic Copy</b>	Due within three (3) months of contract effective date.

All deliveries shall be submitted in electronic format to the following designated NCI Branch Distribution Mailbox: ncibranchcinvoices@mail.nih.gov.

The subject line of the email shall read as follows:

Deliverable\_Contract Number\_Vendor's Name\_Deliverable Description\_Due Date

b. The above items in paragraph a. shall also be addressed and delivered to:

Addressee	Deliverable Item No.	Quantity
Contracting Officer's Representative TBD	1-19	See Quantity for each item above
Contracting Officer National Cancer Institute Office of Acquisitions 8490 Progress Drive, Riverside Five Suite 400 Frederick, MD 21701-4998	1-19	See quantity for each item above

### ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/far> .

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

**52.242-15, Stop Work Order** (August 1989)

**Alternate I** (April 1984) is applicable to this contract.

### SECTION G - CONTRACT ADMINISTRATION DATA

## ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

To be specified prior to award.

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

## ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
TBD	Principal Investigator

## ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

- a. Invoice Submission/Contract Financing Request and Contract Financial Reporting, NIH(RC)-4for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

E-mail: [ncioabbranchcinvoices@mail.nih.gov](mailto:ncioabbranchcinvoices@mail.nih.gov)

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

Central Point of Distribution: NCI Branch C Mailbox

The Contractor shall submit an electronic copy of the payment request to the Central Point of Distribution mailbox. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**
  - a. The original invoice shall be submitted to the following designated billing office:
 

National Institutes of Health  
Office of Financial Management  
Commercial Accounts  
2115 East Jefferson Street, Room 4B-432, MSC 8500  
Bethesda, MD 20892-8500
  - b. One courtesy copy of the original invoice shall be submitted electronically as follows:
    1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
    2. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName\_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Ash Stevens\_Invoice 123456") [Note: Please do not use special characters such as (#, \$, %, \*, &, !) when saving your attachment. Only the underscore symbol (\_) is permitted.]
    3. **Transmit** the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch C - ncibranchcinvoices@mail.nih.gov . Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number\_ Contract Title\_ Contractor's Name\_ unique Invoice number  
  
(e.g, HHSN2612XXXXXC\_Clinical Genetics Support\_Ash Stevens\_Invoice 12345) **[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.]**
2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute .
- b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[ Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- d. Invoice Matching Option. This contract requires a two-way match.
- e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
- f. The Contract Title is:
- Clinical Studies Monitoring Service (CSMS) National Center for Complementary and Integrative Health (NCCIH)
- g. Contract Line Items as follows:

Line Item #	Line Item Description
1	Title: Clinical Studies Monitoring Service (CSMS) National Center for Complementary and Integrative Health (NCCIH); Period of Performance: August 31, 2016 - August 30, 2017

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.
- c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

#### **ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)**

- a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
- b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.
- c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

#### **ARTICLE G.5. INDIRECT COST RATES**

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services  
Office of Acquisition Management and Policy  
National Institutes of Health  
6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663  
BETHESDA MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer.

#### **ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on the anniversary date of the award.

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

<http://www.cpars.gov>

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **ARTICLE H.1. HUMAN SUBJECTS**

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

### **ARTICLE H.2. NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015)**

The Contractor shall not use any funds obligated under this contract to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

(End of clause)

### **ARTICLE H.3. ACKNOWLEDGEMENT OF FEDERAL FUNDING**

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

### **ARTICLE H.4. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

### **ARTICLE H.5. PRIVACY ACT, HHSAR 352.224-70 (December 2015)**

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: [http://www.access.gpo.gov/nara/cfr/waisidx\\_06/45cfr5b\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html).

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm>.

## **ARTICLE H.6. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS**

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

## **ARTICLE H.7. GUN CONTROL**

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

## **ARTICLE H.8. OPTION PROVISION**

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-6, Option for Increased Quantity set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

## **ARTICLE H.9. SUBCONTRACTING PROVISIONS**

### **a. Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated TBD is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

### **b. Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>.

#### **1. Individual Subcontract Reports (ISR)**

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

April 30th  
October 30th  
Expiration Date of Contract

#### **2. Summary Subcontract Report (SSR)**

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

tcrilley@mail.nih.gov  
Contracting Officer

## ARTICLE H.10. CONFIDENTIALITY OF INFORMATION

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

Any data relating to studies being conducted under this contract, including abstracts, preprints and materials to be presented at conferences or public forums.

## ARTICLE H.11. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute,, National Institutes of Health, Department of Health and Human Services, under Contract No. TBD"

## ARTICLE H.12. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The website to file a complaint on-line is: <http://oig.hhs.gov/fraud/hotline/> and the mailing address is:

US Department of Health and Human Services  
Office of Inspector General  
ATTN: OIG HOTLINE OPERATIONS  
P.O. Box 23489  
Washington, D.C. 20026

## PART II - CONTRACT CLAUSES

### SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors>

### ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT

#### ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. **Alternate I** (October 1997) of FAR Clause **52.215-14, Integrity of Unit Prices** (October 2010) is added.
- b. *FAR Clause **52.215-23, Limitations on Pass-Through Charges** (October 2009), is added.*
- c. ***Alternate IV** (October 2010) of FAR Clause **52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (October 2010) is added.*
- d. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (October 2015) is added.
- e. FAR Clause **52.227-14, Rights in Data-General** (May 2014) is deleted in its entirety.
- f. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

#### ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

- a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.204-14, Service Contract Reporting Requirements** (January 2014).
2. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).
3. FAR Clause **52.217-8, Option to Extend Services** (November 1999).  

"..The Contracting Officer may exercise the option by written notice to the Contractor within 30 days.
4. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (October 2014).  

"(c) Waiver of evaluation preference.....  
☐ Offeror elects to waive the evaluation preference."
5. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).
6. FAR Clause **52.222-29, Notification of Visa Denial** (April 2015).
7. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).
8. FAR Clause **52.224-2, Privacy Act** (April 1984).
9. FAR Clause **52.230-2, Cost Accounting Standards** (October 2015).
10. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (October 2015).
11. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).
12. FAR Clause **52.237-3, Continuity of Services** (January 1991).
13. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).
14. FAR Clause **52.246-23, Limitation of Liability** (February 1997).
15. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).
16. FAR Clause **52.248-1, Value Engineering** (October 2010).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015)

**Note:** *The Salary Rate Limitation is at the Executive Level II Rate.*

See the following website for Executive Schedule rates of pay: <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>.

( For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

## 2. HHSAR Clause **352.233-70, Choice of Law (Overseas)** (December 2015)

### c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract: Not applicable.

## **ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT**

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

### a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

#### 1. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (July 2013)

As prescribed in 9.104-7(c), insert the following clause:

- a. The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management (SAM) database at <http://www.acquisition.gov>.
- b. As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIS consists of two segments--
  1. The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--
    - i. Government personnel and authorized users performing business on behalf of the Government; or
    - ii. The Contractor, when viewing data on itself; and
  2. The publicly-available segment, to which all data in the non-public segment of FAPIS is automatically transferred after a waiting period of 14 calendar days, except for--
    - i. Past performance reviews required by subpart 42.15;
    - ii. Information that was entered prior to April 15, 2011; or

- iii. *Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.*
- c. *The Contractor will receive notification when the Government posts new information to the Contractor's record.*
  - 1. *If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.*
  - 2. *The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.*
  - 3. *As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.*
- d. *Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.*

*(End of clause)*

2. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

- a. The Government may extend the term of this contract by written notice to the Contractor within 30 days: provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.
- b. If the Government exercises this option, the extended contract shall be considered to include this option clause.
- c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years.

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

#### SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (Non R & D)	<a href="#">Attach1PackagingandDeliveryInstructions.pdf</a>
Attachment 2:	Proposal Intent Response Sheet	<a href="#">Attach2ProposalIntent.pdf</a>
Attachment 3:	Statement of Work	<a href="#">Attach3SOW.pdf</a>
Attachment 4:	Section K - Representations, Certifications, and Other Statements of Offerors	<a href="#">Attach4SectionK.pdf</a>

#### TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 5:	Summary of Related Activities	<a href="#">Attach5SumRelatedActivities.pdf</a>
Attachment 6:	HHS Section 508 Product Assessment Template	<a href="http://www.hhs.gov/web/508/contracting/technology/vendors.html">http://www.hhs.gov/web/508/contracting/technology/vendors.html</a>

#### BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 7:	Proposal Summary and Data Record, NIH-2043	<a href="#">Attach6ProposedSumDataRec.pdf</a>
Attachment 8:	Small Business Subcontracting Plan	<a href="#">Attach8SmallBusinessContractingPlan.pdf</a>
Attachment 9:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	<a href="#">Attach9SummaryofProposedCosts.xls</a> <a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx</a>
Attachment 10:	Offeror's Points of Contact	<a href="#">Attach10POC.pdf</a>
Attachment 11:	Certificate of Current Cost or Pricing Data	<a href="#">Attach11CCCPD.pdf</a>
Attachment 12:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="#">Attach12DisclosureLobby.pdf</a>

#### INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 13:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	<a href="#">Attach13NIHRC4.pdf</a>
Attachment 14:	Privacy Act System of Records	<a href="#">Attach14PrivacyAct.pdf</a>

## PART IV - REPRESENTATIONS AND INSTRUCTIONS

### SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

#### IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: <http://www.sam.gov> ; and
2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**  
**SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS**  
 which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

3. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

### SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

#### 1. GENERAL INFORMATION

Offerors may submit written questions requesting clarification of the Request for Proposal (RFP) contents. Information provided with each question must include the document name, specific page, paragraph, clause or other definitive citation requiring clarification. All questions must be submitted ELECTRONICALLY to Mary Muir Loesch at [mary.loesch@nih.gov](mailto:mary.loesch@nih.gov) and Tim Crilley at [tcrilley@mail.nih.gov](mailto:tcrilley@mail.nih.gov). FACSIMILE, TELEPHONE OR MAILED QUESTIONS WILL NOT BE ACCEPTED.

Note: It is respectfully requested that all questions be received by March 25, 2016, 3:00PM EDT to allow NCI adequate time to prepare and issue an amendment prior to receipt of proposals. NCI will continue to accept question up to the closing date and time for the RFP. HOWEVER, TIME MAY NOT PERMIT RESPONSES TO QUESTIONS RECEIVED AFTER March 25, 2016, 3:00PM EDT to be prepared and issued prior to receipt of proposals.

#### a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2006)]

##### a. *Definitions. As used in this provision--*

*"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.*

*"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.*

*"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.*

*"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.*

*"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.*

- b. Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).*
- c. Submission, modification, revision, and withdrawal of proposals.*
  - a. Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.*
  - b. The first page of the proposal must show--*
    - i. The solicitation number;*
    - ii. The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);*
    - iii. A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;*
    - iv. Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and*
    - v. Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.*

### *3. Submission, modification, revision, and withdrawal of proposals.*

*(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.*

*(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--*

*(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or*

*(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or*

*(3) It is the only proposal received.*

*(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.*

*(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.*

*(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.*

*(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.*

*(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.*

*(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.*

*(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.*

*(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.*

*(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.*

*(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).*

*(e) Restriction on disclosure and use of data.*

*(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:*

*"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human*

*Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.*

*The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.*

*If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.*

*The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages ( insert page numbers, paragraph designations, etc. or other identification)."*

*(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:*

*"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."*

*(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).*

*(f) Contract award.*

*(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.*

*(2) The Government may reject any or all proposals if such action is in the Government's interest.*

*(3) The Government may waive informalities and minor irregularities in proposals received.*

*(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.*

*(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.*

*(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.*

*(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.*

*(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.*

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

- (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
  - (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
  - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
  - (iv) A summary of the rationale for award.
  - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
  - (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.
- (End of Provision)

**Alternate I** (October 1997).As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

#### **b. NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541990.
2. The small business size standard is \$15 Million..

**THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS.** However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

#### **c. TYPE OF CONTRACT AND NUMBER OF AWARDS**

1. It is anticipated that [one/multiple award(s)] will be made from this solicitation and that the award(s) will be made on/about August 31, 2016.
2. It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a base year and four (4) one-year options, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

**d. ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this SOLICITATION. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 26,800 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

Year	Estimated Labor Hours
Base	5,360
Option 1	5,360
Option 2	5,360
Option 3	5,360
Option 4	5,360

**e. COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

**f. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this SOLICITATIONS. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

**g. RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

**h. PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

**i. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2**

- (a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer  
 Office of Acquisitions  
 National Cancer Institute  
 National Institutes of Health Room 4046  
 8490 Progress Drive, Suite 400  
 Frederick, MD 21701- 4998

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

## **2. INSTRUCTIONS TO OFFERORS**

### **a. GENERAL INSTRUCTIONS**

#### **INTRODUCTION**

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

#### **1. Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

#### **2. Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

##### **I. COVER PAGE**

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

##### **II. TECHNICAL PROPOSAL**

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

##### **III. BUSINESS PROPOSAL**

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

### 3. **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

### 4. **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

### 5. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

### 6. **Evaluation of Proposals**

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

### 7. **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

### 8. **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

**Hard Metric** - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

**Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

**Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

## 9. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this SOLICITATION pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

## 10. Selection of Offerors

- a. The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -
  1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR Part 315.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the SOLICITATION. In addition, the SOLICITATION may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

#### 11. **52.203-98 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements--Representation (DEVIATION)**

- a. In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Resolution Appropriations Act, 2015 (Pub. L. 113-235), Government agencies are not permitted to use funds appropriated (or otherwise made available) under that or any other Act for contracts with an entity that requires employees or subcontractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.
- b. The prohibition in paragraph (a) of this provision does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.
- c. Representation. By submission of its offer, the Offeror represents that it does not require employees or subcontractors of such entity seeking to report fraud, waste or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. (End of provision)

#### 12. **Past Performance Information**

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last five (5) contracts completed during the past THREE years and ALL CONTRACTS currently being performed that are similar in nature to the solicitation workscope.

Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as a subcontract with a value of \$250,000 or more.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

**13. Electronic and Information Technology Accessibility Notice, HHSAR 352.239-73 (December 2015)**

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.
- b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.
- c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies

conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site <http://www.hhs.gov/web/508>. In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

- d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

#### 14. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Data Universal Numbering System Number, FAR Provision 52.204-6 (July 2013).
- b. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).
- c. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- d. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).
- e. Certification Regarding Trafficking in Persons Compliance Plan, FAR Provision 52.222-56 (March 2015)

#### b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

**Note to Offerors:** Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

## 1. Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

### a. Statement of Work

#### 1. Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

#### 2. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

#### 3. Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

#### 4. Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

### b. Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program

**OFFERORS SHOULD ASSURE THAT THE PROJECT DIRECTOR/MANAGER, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.**

**1. Project Director/Manager**

List the name of the Project Director/Manager responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be staff, identify the Project Director/Manager who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Project Director/Manager. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

**2. Other Professional Personnel**

List all other professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

**3. Additional Personnel**

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

**4. Resumes**

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

**2. Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

### 3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

### 4. Instructions to Offerors-Sustainable Acquisition:

HHSAR Provision **352.223-71** (December 2015) is not applicable to this requirement. No green products or services will be used in the acquisition as there is no opportunity to acquire green products or services.

## c. BUSINESS PROPOSAL INSTRUCTIONS

### 1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

### 2. Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and

9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

**3. Data Other than Certified Cost or Pricing Data**

- a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

- b. The data submitted shall be at the level of detail described below.

**a. Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

**b. Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

**c. Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$700,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

**d. Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

**e. Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

**f. Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

**g. Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

**h. Special Equipment**

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

**i. Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

**j. Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

**Alternate I** (October 2010) of FAR Clause **52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data** (October 2010). As prescribed in 15.408(l)(and see 15.403-5(b)(1)), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in the following format:

The format specified in paragraph L.2.c.4. Certified Cost or Pricing Data, subparagraph 3. formats for Submission of Line Item Summaries shall be used for the submission of cost data. Submission of all other certified cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

**4. Salary Rate Limitation**

Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II\* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or

other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II\*. The Executive Schedule, Level II\* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants. **LINK TO EXECUTIVE SCHEDULE RATES OF PAY:**

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>

*(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

**\*Note to Offerors:** The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

## 5. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$650,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
  1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
  2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
  3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
  4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
  6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
  2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
  3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
  4. A description of the method used to develop the subcontracting goals.
  5. A description of the method used to identify potential sources for solicitation purposes.
  6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
  7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
  8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
  9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$650,000 adopt a plan similar to the plan agreed upon by the offeror.
  10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.
  11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan,

and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

33% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

#### **6. Mentor-Protégé Program, HHSAR 352.219-70 (December) 2015**

- a. Large business prime contractors serving as mentors in the HHS Mentor-Protege Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protége agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protege firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at [www.esrs.gov](http://www.esrs.gov). The mentor firm and protege firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a \$10,000 subcontract awarded to a protege firm and provision of \$5,000 of developmental assistance as \$15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.
- b. The program consists of--
  1. Mentor firms--large businesses that:
    - (i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
    - (ii) Have a Mentor-Protege agreement approved by HHS' OSDBU;
  2. Protege firms--firms that:
    - (i) Seek developmental assistance;
    - (ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
    - (iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and
  3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

#### **7. HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

## 8. Total Compensation Plan

### a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

### b. Evaluation

#### 1. Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

#### 2. Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

#### 3. Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

#### 4. Federal Acquisition Regulation Clauses incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

## 9. Other Administrative Data

### a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

### 2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

**NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.**

### 3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: <https://web.archive.org/web/20111015044731/http://www.hhs.gov/hhsmanuals/>.

**b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (JULY 2013)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than System for Award Management.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of Provision)

**c. Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

**d. Adequate Accounting System**

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:

- Proper segregation of direct costs from indirect costs.
- Identification and accumulation of direct costs by contract.
- A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
- Accumulation of costs under general ledger control.
- A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
- A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
- Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
- Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
- Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
- Segregation of preproduction costs from production costs, if applicable.
- Accounting system provides financial information:
  - Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
  - Required to support requests for progress payments.
- Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.
- Accounting system is currently in full operation.

The Contracting Officer reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror's accounting system is compliant as certified above.

**e. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)**

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

☐ **Fac Cap Cost of Money (Has)** The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

☐ **Fac Cap Cost of Money (Has Not)** The prospective Contractor **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

## 10. Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

### a. General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

### b. Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

### c. Performance History

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

### d. Pertinent Contracts

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

### e. Pertinent Grants

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

## 11. Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a. Willingness to perform as a subcontractor for specific duties (list duties).

- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

**12. Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

**13. Travel Costs/Travel Policy**

**a. Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

**b. Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

## **SECTION M - EVALUATION FACTORS FOR AWARD**

### **1. GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the SOLICITATION. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below. Technically acceptable proposals will not be considered for award.

### **2. COST/PRICE EVALUATION**

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.

### **3. EVALUATION OF OPTIONS**

It is anticipated that any contract awarded from this solicitation will contain option provisions and periods.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the options.

### **4. TECHNICAL EVALUATION FACTORS**

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are listed in order of relative importance.

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

#### **1. TECHNICAL PLAN/APPROACH**

**45 points**

An offeror shall be evaluated on their ability to adequately demonstrate the appropriateness, adequacy, soundness and feasibility of proposed plans and procedures and capabilities for carrying out the functions specified in the Statement of Work as evidenced by the following:

#### A. Clinical Site Monitoring and Reporting

- i. organizational experience in planning and conducting the breadth of routine and specialized clinical site and study monitoring visits required, including experience in the identification and resolution of site performance problems and deficiencies
- ii. proposed Standard Operating Procedures (SOPs) for both routine and specialized clinical site monitoring visits
- iii. proposed approach to scheduling clinical site monitoring visits, the cost/resource efficiencies of the proposed approach, and experience in and approaches implemented to resolve scheduling problems and conflicts
- iv. plans and approaches for accommodating urgent and/or unanticipated site monitoring needs.
- v. organizational experience with and proposed plans and procedures for coordinating clinical site monitoring functions

#### B. Training

- i. proposed Training Plan for all training activities to be conducted for site monitors on staff as well as newly hired monitors
- ii. proposed plan for evaluating training activities, including performance metrics
- iii. organizational experience in planning and conducting training for site monitors

#### C. Quality Assurance/Quality Control (QA/QC)

- i. proposed QA/QC Plan for standardizing contract processes, ensuring compliance with domestic and country-specific regulations and Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines, and assessing Contractor performance and the quality of clinical site monitoring functions performed
- ii. results of independent audits conducted over the past 5 years, problems/deficiencies identified, and correct/remedial actions implemented to resolve identified problems and deficiencies

## 2. PROJECT MANAGEMENT

**30 points**

#### A. Project Management Personnel

The adequacy and appropriateness of the training, experience, qualifications and availability of the proposed project management personnel, particularly with respect to the coordination, management and oversight of clinical site monitoring functions for large and complex clinical studies or programs involving both domestic and foreign clinical sites, including clinical sites in resource-limited countries

- i. Program Director - includes training and experience in overall project management and communications, tracking, monitoring and reporting on project status and progress, recommending modifications to project requirements, timelines and procedures, and directing and ensuring the quality of site monitoring functions carried out by in-house staff as well as subcontractors, and implementing corrective/remedial actions to resolve problems and deficiencies.
- ii. Senior Project Manager - includes training and experience in overseeing the daily operations of large and complex projects, tracking assignments, ensuring adherence to internal policies and procedures, and assisting in the resolution of deficiencies and problems.
- iii. Administrative Personnel - includes training and experience in financial management and reporting on all contract activities, including activities carried out by subcontractors.

**B. Integrated Master Project Plan**

The appropriateness, adequacy, feasibility and soundness of the proposed Integrated Master Project Plan with respect to the following Plan components:

- i. Management Structure - including roles and responsibilities of proposed staff of the offeror and all subcontractors, lines of authority and plans for achieving appropriate and ongoing communications among project staff.
- ii. Project Implementation and Management - encompasses proposed plans for implementing and managing all contract activities, including project management systems and procedures and proposed plans for assessing the efficiency of internal project management procedures in the following areas: (i) internal timelines for planning and implementing contract assignments and metrics for assessing efficiency and timeliness; (ii) personnel and other resources required and methods to assess the adequacy of contract resources; (iii) project risks and risk management/mitigation strategies; (iv) initial and ongoing training of clinical, technical and project management staff on Project Implementation and Management procedures and timelines; and (v) procedures to ensure that all Contractor and subcontractor staff safeguard intellectual property, the confidentiality of human subjects and other data, and other information provided by third parties or by the Government, as well as data generated through this contract.

**C. Subcontract Management and Reporting:**

The adequacy and appropriateness of the proposed plan for the management and oversight of all contract activities carried out by subcontractors, including proposed procedures for monitoring the timeliness, accuracy and completeness of the work carried out, identifying problems and deficiencies, developing and implementing corrective/remedial actions, and reporting to NCCIH/OCRA on subcontractor performance.

**3. CLINICAL AND TECHNICAL PERSONNEL****25 points**

A. An offeror shall be evaluated on their ability to demonstrate the suitability and adequacy of the qualifications, experience, training, and availability of proposed clinical and technical personnel to accomplish the requirements specified in the Statement of Work, particularly with respect to large and complex clinical trial programs involving both domestic and foreign clinical sites, including clinical sites in resource-limited countries:

- i. Site Monitors - includes training and experience in clinical site monitoring for (i) clinical trials conducted at both domestic and foreign sites in resource-limited countries, (ii) clinical trials conducted in a variety of community- and hospital-based settings, and (iii) proficiency in the language of countries where clinical records are not maintained in English.
- ii. Lead Site Monitor - includes experience and training in performing clinical site monitoring functions as well as experience and expertise in coordinating, tracking, managing and assessing the performance and quality of clinical site monitoring activities and personnel.
- iii. Information Technology Manager - includes experience and expertise to ensure appropriate interface with multiple databases of clinical trial sponsors, networks and support contractors.

B. The appropriateness and adequacy of proposed plans for the identification and recruitment of the number of additional site monitors proposed to be hired to ensure that 100% of site monitors are on board and trained within 4 months of the contract effective date.

C. The adequacy of documentation of the ability to recruit and retain site monitors based on organizational performance over the past 5 years.

D. Appropriateness of plans for cross-training and replacement of proposed staff throughout the course of the contract, including back-up and fill-in personnel.

**E. Facilities, Equipment And Other Resources**

- i. Location and features of office space and facilities, including lease or ownership information
- ii. Proposed plans and procedures to accommodate the need for NCCIH to have easy and rapid access to contract staff and documents housed at the offeror's main facility or satellite office and the cost-effectiveness of the proposed plans and procedures
- iii. The rationale for the number and locations of proposed regional or local field offices outside of the U.S., including how such arrangements are expected to contribute to cost-effectiveness and efficiency in the use of contract resources and to ensure adequate access to site monitoring staff expertise and assistance by foreign sites
- iv. Adequacy of security arrangements for protecting the confidentiality of the records.

**TOTAL POSSIBLE WEIGHT**

**100 points**

## **5. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508**

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

## **6. PAST PERFORMANCE FACTOR**

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

When assessing performance risks, the Government, to the fullest extent practicable, will focus on the past performance of the offeror as it relates to all acquisition requirements, in terms of Quality, Schedule, Cost Control, Business Relations, Management, Small Business and Other factors as deemed appropriate.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.